UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: February 25, 2011

SUBJECT: Preliminary Human Health Assessment for the Registration Review of Putrescent Whole Egg Solids

Registration Review Case #: 4079
PC Code: 105101
Chemical Class: Biochemicals

FROM: Sadaf Shaukat, Biologist
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

The following is a preliminary human health assessment for putrescent whole egg solids in support of the development of the Registration Review Work Plan.

RECOMMENDATIONS AND CONCLUSIONS

Executive Summary

Based on the available data and information, the Agency does not foresee the need for new data or for a new human health risk assessment for this active ingredient. Hazard and exposure information as well as Agency risk assessments on putrescent whole egg solids were evaluated against current safety standards established by the Agency's scientific policies and regulations and it was determined that there is no need to conduct an additional human health risk assessment. Fresh eggs and egg products are Generally Recognized as Safe (GRAS) (21 CFR 170.3) by FDA. Also, egg solids are recognized as a common human food or significant component of a common human food. According to the Incident Data System, there have been no reports of incidents from use of products containing putrescent whole egg solids as an active ingredient. There is reasonable certainty that no harm will result to the general population from exposure to putrescent whole egg solids in the products containing this active ingredient when they are used according to label instructions.

I. Toxicity Profile

Although data on the technical grade of the active ingredient (TGAI) are required under 40 CFR 158.2050, because putrescent whole egg solids are considered to be of minimum risk and have a significant history of exposure to humans, toxicology data on this active ingredient historically has been waived. Based on the available information on this biochemical and its current uses as a pesticide, the Agency will continue to waive generic toxicology data requirements for the TGAI. However, toxicology data requirements must be fulfilled for manufacturing products (MPs) end-use products (EPs) containing this active ingredients Toxicology data and or rationale to fulfill or waive these requirements are available on the currently registered EPs; all of which indicate that these products are of low toxicity.

All toxicology data requirements have been satisfied and it is unlikely that any additional data will be required. Toxicology data and or rationale to fulfill or waive these requirements are available on the currently registered EPs; all of which indicate that these products are of low toxicity.

Please see the tables below for detailed information regarding the toxicity data requirements of registered end-use products.

Available toxicity data as required by 40 CFR 158.2050 regarding putrescent whole egg solids are summarized below in Tables 1-6.

Table 1. Putrescent Whole Egg Solids: Acute Oral Toxicity/OPPTS 870.1100

LD_{50}	Toxicity Category	MRID
>5,000 mg/kg	IV	46295003
Adequate information submitted to support data requirement	IV	47417806
>5,000 mg/kg	IV	46032706
>5,000 mg/kg	IV	47357705

Table 2. Putrescent Whole Egg Solids: Acute Dermal Toxicity/OPPTS 870.1200

LD_{50}	Toxicity Category	MRID
>2,000 mg/kg*	III*	42693802
>5,000 mg/kg	IV	46295004
>2,000 mg/kg*	III*	47417807
>5,000 mg/kg	IV	46032707
>5,000 mg/kg	IV	47357706

* 2,000 mg/kg was the highest dose tested in the study

Table 3. Putrescent Whole Egg Solids: Acute Inhalation Toxicity/OPPTS 870.1300

LC_{50}	Toxicity Category	MRID
>2.10 mg/L	IV	46295005
>2.08 mg/L	IV	47417808
>2.08 mg/L	IV	46032708

Table 4. Putrescent Whole Egg Solids: Acute Eye Irritation/OPPTS 870.2400

Results	Toxicity Category	MRID
Corneal irritation clearing within 7 days or less	III	46295006
Corneal irritation clearing within 48 hours	III	47417809
Corneal irritation clearing within 4 days	III	43311401
Corneal irritation clearing within 72 hours	III	46032709
Corneal irritation clearing within 48 hours	III	47357709

Table 5. Putrescent Whole Egg Solids: Acute Dermal Irritation/OPPTS 870.2500

Results at 72 hrs	Toxicity Category	MRID
Slight irritation	IV	46295007
Slight irritation	IV	47417810
Slight irritation	IV	43311402
Moderate irritation	III	46032710
Slight irritation	IV	47357710

Table 6. Putrescent Whole Egg Solids: Skin Sensitization/OPPTS 870.2600

Results	MRID
0.4 mL Is a Skin Sensitizer	46295008
Not a Sensitizer	47417811
Is a Skin Sensitizer*	46032711
Not a Sensitizer	47357711
Is a Skin Sensitizer*	47357712

*Putrescent Whole Egg Solids was not the only a.i. in these products

Based on the information presented above, the Agency does not foresee the need for new data or for a new human health risk assessment. There is reasonable certainty that no harm will result to the general population from exposure to putrescent whole egg solids in the products containing this active ingredient when they are used according to label instructions.

V. References

U.S. EPA RED-Putrescent Whole Egg Solids. Issued June, 1992.

cc: *S. Shaukat, M. Adams*, BPPD Science Review File
S. Shaukat, FT, PY-S: 2/25/11